Amdt

1615

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Brubaker
Application No.	:	10/034,795
Filed	:	December 27, 2001
Title	:	Sustained Release Drug Delivery Devices with Prefabricated Permeable Plugs
Group/Art Unit	:	1615
Examiner	:	Robert M. Joynes
Conf. No.	:	1325
Docket No.	:	P02971

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited in the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P. O. Box 1450, Alexandria, Virginia 22313-1450, on March 31, 2004.

Suzanne V. Saracen

FIRST RESPONSE TO NON-FINAL OFFICE ACTION

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Examiner:

A. INTRODUCTION

This Communication filed in response to the Office Action dated January 15, 2004, is timely filed within the three-month time period for response, which time period is set to expire on April 15, 2004. Reconsideration of this application is requested in view of the foregoing amendments and the following remarks. Claims 1-37 are pending in the present application and have not been amended.

B. POWER OF ATTORNEY

Undersigned Attorney, Paul Lavoie hereby enters an appearance on behalf of Applicants. Attached is a power of attorney signed by a duly authorized representative of Assignee/Owner Bausch & Lomb.

C. NON-STATUTORY DOUBLE PATENTING

Claims 1-37 of the subject application were provisionally rejected under the doctrine of obviousness-type double patenting as being unpatentable over co-pending application U.S. Serial No. 10/378,374, U.S. Ser. No. 10/023,391 and U.S. Serial No. 10/035,095. Applicant, through his attorney of record, has executed and submitted a terminal disclaimer to address the non-statutory double patenting rejections. Accordingly, this rejection is now moot.

D. CLAIM REJECTIONS 53 USC 103

Claims 1-31 were rejected under 35 USC 103(a) as being unpatentable over U.S. Patent No. 5,378,475 (Smith). Applicant respectfully traverses this rejection because the Examiner has not established a *prima facie* case of obviousness. Furthermore, the differences between the devices taught in Smith and the devices set forth in the present application represents a significant improvement over the state of the art as taught by Smith.

The Examiner bears the burden of establishing a *prima facie* case of obviousness. To establish the *prima facie* case of obviousness, each and every element of the present invention must be found in the prior art as evidenced, for example, by prior art references. Not all of the elements of the claimed invention are found in Smith.

a. Claims 1-11 Are Not Obvious

Claim 1 sets forth a sustained release drug delivery device. The device comprises a drug core comprising a therapeutically effective amount of at least one agent effective in obtaining a diagnostic effect or effective in obtaining a desired local or systemic physiological or pharmacological effect. The device further comprises a unitary cup essentially impermeable to the passage of the agent. The unitary cup surrounds and defines an internal compartment to accept the drug core. The unitary cup comprises an open top end with at least one recessed groove around at least some portion of the open top end of the unitary cup. A prefabricated plug that is permeable to the passage of the agent is positioned at the open top end of the unitary cup. The groove on the cup interacts with the prefabricated plug holding the plug in position and closing the open top end. The prefabricated plug allows passage of the agent out of the drug core through the prefabricated plug and out the open top end of the unitary cup. Claims 2-11 depend from claim 1 and contain all of the elements of claim 1.

The Smith reference does not teach a unitary cup that comprises an open top end with at least one recessed groove and a prefabricated plug that is permeable to the passage of said agent wherein the groove on the cup interacts with said prefabricated plug holding the plug in position.

Rather, Smith teaches a sustained release drug delivery device comprising a drug core coated with a first layer which is coated with a second layer. One of the layers is a drug impermeable layer that partially surrounds the drug core. The other layer is a permeable layer that completely surrounds the drug core. In one embodiment, the first layer is impermeable and the second layer is permeable. In another embodiment, the first layer is permeable and the second layer is impermeable.

Nowhere in Smith does it teach a groove on a cup that interacts with the prefabricated plug holding the plug in place. This differences between the designs taught in Smith and the device set forth in claim 1 (and the claims that depend upon claim 1) are significant.

When the device taught in Smith is inserted into a patient, the drug permeable layer will take up more water than the drug impermeable layer. The differential in water uptake between the permeable layer and the impermeable layer puts a strain on the adhesive joint between the two layers. In some instances, the adhesive can fail causing the impermeable layer to separate from the permeable layer. When the two layers separate, the impermeable layer will be less effective at restricting the rate of release of the drug. Variances in the release rates are likely to occur—particularly after the device remains *in-vivo* for longer periods of times.

In contrast, the present invention as set forth in claim 1 has a groove that interacts with said prefabricated plug holding the plug in position. The interaction between the groove and the cap is stronger under *in-vivo* conditions and more heartily resists the separation of the permeable layer from the impermeable layer than a multi-layered coating. While the benefit of the present invention is not restricted to a particular period of time, the present device can be implanted for longer periods of time with less variance than the multi-layered coating design of Smith.

Thus, the Examiner has failed to establish a *prima facie* case of obviousness of claim 1 of the present invention. Furthermore, because the present invention creates a potentially more reliable drug delivery device than Smith, the differences between the device taught in Smith and the device of claim 1 represent a significant technical improvement set forth in claim 2 defining

an unexpected result. Allowance of claim 1, and claims 2-11 that depend from claim 1 is respectfully requested.

b. Claims 12-23 Are Not Obvious

Claim 12 sets forth a sustained release drug delivery device. The device comprises drug core having at least one agent effective in obtaining a diagnostic effect or effective in obtaining a desired local or systemic physiological or pharmacological effect. A unitary cup that is essentially impermeable to the passage of the agent surrounds and defines an internal compartment to accept the drug core. The unitary cup comprises an open top end and at least one lip around at least a portion of the open top end of the unitary cup. There is a prefabricated plug that is permeable to the passage of the agent. The prefabricated plug is positioned at the open top end of the unitary cup wherein the lip interacts with the prefabricated plug. The interaction holds the prefabricated plug in position and closes the open top end. The permeable plug allows passage of the agent out of the drug core, through the permeable plug and out of the open top end of the unitary cup. Claims 13-23 depend from claim 12 and contain all of the elements of claim 12.

The Smith reference does not teach a unitary cup that comprises an open top end with at least one lip around at least a portion of the open top end and a prefabricated plug that is permeable to the passage of said agent wherein the lip on the cup interacts with said prefabricated plug holding the plug in position.

Rather, Smith teaches a sustained release drug delivery device comprising a drug core that is coated with a first layer which in turn is coated with a second layer. One of the layers is a drug impermeable layer that partially surrounds the drug core. The other layer is a permeable layer that completely surrounds the drug core. In one embodiment, the first layer is impermeable and the second layer is permeable. In another embodiment, the first layer is permeable and the second layer is impermeable.

Nowhere in Smith does it teach a lip on a cup that interacts with the prefabricated plug holding the plug in place. The differences between the devices taught in Smith and the device set forth in claim 12 (and the claims that depend upon claim 12) are significant.

When the devices taught in Smith are inserted into a patient, the drug permeable layer will take up more water than the drug impermeable layer. The differential in water uptake

between the permeable layer and the impermeable layer puts a strain on the adhesive joint between the two layers. In some instances, the adhesive can fail causing the impermeable layer to separate from the permeable layer. When the two layers separate, the impermeable layer will be less effective at restricting the rate of release of the drug. Variances in the release rates are likely to occur—particularly after the device remains *in-vivo* for longer periods of times.

In contrast, the present invention as set forth in claim 1 has a lip that interacts with said prefabricated plug holding the plug in position. The interaction between the lip and the cap is stronger under *in-vivo* conditions and more heartily resists the separation of the permeable layer from the impermeable layer than a multi-layered coating taught in Smith. While the benefit of the present invention is not restricted to a particular period of time, the device of claim 12 can be implanted for longer periods of time with an expectation of less variance in the rate of drug delivery than the multi-layered design taught in Smith.

Thus, the Examiner has failed to establish a *prima facie* case of obviousness of claim 12 of the present invention. Furthermore, because the present invention creates a potentially more reliable drug delivery device than Smith, the differences between Smith and the device of claim 12 represent a significant technical improvement defining an unexpected result. Allowance of claim 12, and claims 13-23 that depend from claim 12 is respectfully requested.

c. Claims 24-27 Are Not Obvious

Independent claim 24, as well as claims 25-27 which depend from claim 24, teaches a method of providing controlled and sustained administration of an agent that comprises, among other things, inserting a drug delivery device in the body of a mammalian organism. The drug delivery device has a drug core and a unitary cup that is essentially impermeable to the passage of the agent. The unitary cup has an open top end with at least one recessed groove. A prefabricated plug interacts with the groove to hold the prefabricated plug in position. Some of the same reasons relating to the patentability of claim 1 set forth above also apply to the method of claim 24 as well as claims 25-27. To the extent that the above arguments pertain to the language of claim 24, the arguments above are incorporated herein by reference. Allowance of claims 24-27 is respectfully requested.

d. Claims 28-31 Are Not Obvious

Independent claim 28, as well as claims 29-31 which depend from claim 28, teaches a method of providing controlled and sustained administration of an agent that comprises, among other things, inserting a drug delivery device in the body of a mammalian organism. The drug delivery device has a drug core and a unitary cup that is essentially impermeable to the passage of the agent. The unitary cup has an open top end with at least one lip. A prefabricated plug interacts with the lip to hold the prefabricated plug in position. Some of the same reasons relating to the patentability of claim 12 set forth above also apply to the method of claim 28 as well as claims 29-31. To the extent that the arguments above pertain to the language of claim 28, they are incorporated herein by reference. Allowance of claims 28-31 is respectfully requested.

* * *

In view of the foregoing arguments, Applicant believes that the application is in condition for allowance. An early and favorable action on the merits is solicited.

Respectfully submitted,

Dated: March 31, 2004

Paul T. Lavoie
Attorney for Applicant
Registration No. 38,681

BAUSCH & LOMB INCORPORATED
One Bausch & Lomb Place
Rochester, NY 14604-2701
Telephone: (585) 338-6353
Facsimile: (585) 338-8706
Email: Paul_T_Lavoie@bausch.com